

INITIAL STATEMENT OF REASONS

This emergency regulatory change is necessary to implement the requirements of Budget Act of 2000-2001 and the 1999 changes to the Health and Safety Code relating to the establishment of fees for National Environmental Laboratory Accreditation Program (NELAP). The accreditation of environmental laboratories under NELAP is required by Senate Bill 1304 (Chapter 372, Statutes of 1999).

This regulation change in Title 22, California Code of Regulations, implements Section 100862, Division 101, Part 1, Chapter 4, Article 3 of the Health and Safety Code. The new statute enables the Department to recognize environmental laboratories in California under NELAP. The new national program establishes nationwide standards for environmental laboratories (US EPA publication number EPA600/R-99/068, July 1999). The new statute requires the establishment of a schedule of fees to fully support the new accreditation program in California.

Laboratories accredited under this program are able to perform environmental testing in any state which has been recognized by the NELAP as an authorized accrediting authority. To become qualified for NELAP accreditation, which is voluntary on the part of each laboratory, the laboratory must meet a number of uniform nationwide requirements. Participation in the national program is expected to improve, on a nationwide basis, the quality of environmental laboratory analyses, and reduce or eliminate inconsistent regulatory standards and accreditation requirements which are currently required of laboratories which operate in more than one state.

This regulation change establishes a schedule of fees to be paid by laboratories accredited under this program. Because the statute requires that the program be self-supporting through fees, the establishment of the fee schedule is essential. The Budget Act for 2000-2001 (AB 1740, Chapter 52, Statutes of 2000), provision 2 to Item 4260-001-0001, requires that the department promulgate emergency regulations to adjust fees that otherwise would not be sufficient to support a fully fee supported program at least at the 95% level. Without the fees established in this regulation, the Department's NELAP accreditation program would not be fully supported by fees from the regulated laboratories and, consequently, could not be most effectively implemented.

This change will help protect the health and safety of Californians by providing a mechanism enabling California laboratories to fully participate in the national program. This provides recognition by California of national standards that are accepted throughout the nation.

The Department's existing certification program for environmental laboratories remains essentially unchanged, since participation in NELAP is voluntary. However, if a laboratory selects the NELAP accreditation process, that laboratory no longer is required to maintain a separate departmental certification unless the

laboratory wishes to conduct environmental laboratory tests which are not covered by the NELAP standards.

The specific regulation changes are as follows:

(a) Add a new Article 16, National Environmental Laboratory Accreditation Program, containing Section 64860.

(b) Adopt a new section 64860 to provide for a schedule of fees payable by applicants for and holders of NELAP accreditations, as required by Health and Safety Code Section 100862(a). The NELAP program, which is voluntary on the part of laboratories, is more comprehensive and costly to administer than the existing departmental certification program. The new fee schedule takes this into account and establishes fees that are expected to return funds sufficient to administer the NELAP program.

In developing the fee schedule set forth in Section 64860(a), the Department has made the determination that there should be a basic or administrative fee of \$3000. This is approximately three times the basic administrative fee for certification under the existing state program. The Department has observed, based on processing the applications and preparing for the site assessments as part of the NELAP program, that the program is spending two to three times the effort on the initial application and document review than it has in the past for the state certification program. This is in part due to the lengthy documentation which is required by the federal NELAC standards. As an example, for ELAP certification, quality assurance and good laboratory practices are covered, during the site visit, by a checklist of five or six pages. For NELAP accreditation, the laboratory has to prepare a forty page checklist covering the same information which the program must review even before conducting the site assessment.

Also, NELAP requires an accreditation renewal every twelve months, whereas departmental certification is only once every twenty-four months. This adds to the overall basic administrative costs for NELAP. In addition, NELAP applications are considerably more detailed than those of the Department, and an additional exchange of information with NELAP when applications are evaluated is required.

In both the NELAP and departmental programs, on-site visits are conducted once every two years. However, NELAP on-site visit protocols and documentation are much more detailed and complex. Therefore, it was determined that Field of Testing (FoT) fees required by the statutes should be based on the complexity/work effort of evaluating and inspecting the equipment, methods and personnel involved in the various FoTs, rather than having the same fee for each category. The Fields of Testing have been modified by the new changes in the Health and Safety Code. The fee schedule for FoTs takes into consideration the various complexities of analyses required for laboratories to determine the

presence of environmental contaminants in the media being tested. The costs to the Department to evaluate and monitor a laboratory's ability to measure accurately environmental samples vary depending on the complexity of the FoTs.

The new regulation establishes fee levels as follows: \$750 for each FoT considered to be of simple complexity; \$1000 for each FoT considered to be of medium complexity; and \$1800 for each FoT considered to be of high complexity. In order to determine appropriate fee levels, the Department took into account the historic data that it has obtained by conducting site assessments for the ELAP program over the last ten years, as well as the costs incurred in site assessments and application evaluations for a sample of laboratories that are currently in the process of applying for NELAP accreditation (see the later discussion under Fee Determination/Fiscal Impact Estimate). Time records were kept of the number of hours required for site visits to these laboratories, and the laboratories were evaluated based on the complexity of the FoTs in the individual laboratories. From prior departmental certification program experience it is known that, with biennial onsite visits, the ratio of first year costs to second year costs is about 100:55. In both programs, full on-site visits are being conducted once every two years. Fees are collected on an annual basis. The fee levels being established are based on the average annual cost for each two-year period. An analysis of this sample of laboratories applying for NELAP accreditation, plus prior Departmental experience with the existing certification program, then, has demonstrated that the departmental staff should be able to function effectively with the funds derived through the new fee schedule.

Simple complexity FoTs are those which can be measured by relatively easy-to-conduct tests and measurements, using instruments that are less complicated and easier to calibrate. Medium complexity FoTs are those which require more time and effort to accurately measure the potential level of hazardous contaminants, which require more sophisticated instrumentation, and more skill in operating and calibrating the measuring equipment. High complexity FoTs are those which demand the most sophisticated instrumentation, the most skilled instrument operators, and/or have the greatest degree of potential harm to health and safety if not measured to the highest degree of accuracy. The initial estimates of fees have been adjusted based on the experiences gained during the site assessments conducted with the laboratories which are seeking to be in the first group to receive NELAP accreditation. The two FoTs which cover aquatic bioassay testing, N113 (Whole Effluent Toxicity of Wastewater) and N119 (Toxic Bioassay of Hazardous Waste) were initially assigned to the Low Complexity group. After examining the data collected from the assessors it was noted that a bioassay laboratory was taking approximately 50% more time than a laboratory of comparable size which did not do aquatic bioassay, and this time was for an Environmental Specialist III, a higher grade position than of the usual Public Health Chemist II's who do the majority of the site assessments. Based on this observation the Department decided to reassign the aquatic bioassay FoTs from the Simple Complexity' to the Medium Complexity.

In the Department's evaluations of the various Fots, to determine the appropriate levels of funding necessary to maintain adequate control for public health purposes, it was found that the low complexity Fots will cost approximately 75% of the cost of the medium complexity Fots. The high complexity Fots, on the other hand, will cost approximately 80% more than the cost of overseeing the medium complexity Fots. The total income to be achieved as a result of the collection of these fees, then, will approximate the total cost to the Department to administer the NELAP accreditation program in the state.

A new subsection 64860(b) has been added to make it clear that the fees required to support the new NELAP activities must be paid to the Department before the accreditation is granted. This is critical to the Department in order to have sufficient funds on hand to carry out the assessment and oversight activities required by the law. Although H&S Code section 100862(a) already states that fees shall be paid prior to the granting of an accreditation, the Department believes that it will avoid unnecessary correspondence and communications with applicants, and resulting delays, if this is restated in the regulation for clarity purposes.

Fee Determination/Fiscal Impact Estimate

The Department believes there will be no major fiscal impact as a result of this regulation. Health & Safety Code Section 100860 state that fees payable to the Department from the regulated industry must be sufficient to support the certification and accreditation programs. Although there will be an increase in departmental workload to meet NELAP accreditation standards and enforcement requirements, these costs will be offset by increased fees to be paid by laboratories which wish to become NELAP accredited. Laboratories, which do not wish to become NELAP accredited, may continue to maintain their ELAP certification and will not have any increase in fees as a result of this regulation.

This regulation does establish new fees, as authorized and required by the Health and Safety Code. And the fees must, as provided in the statutes, be sufficient to recover the costs of administering the national accreditation program. However, because the national accreditation program is not required, but is voluntary, any laboratory that does not wish to pay the new fees, which are higher than those required for the ELAP program, does not have to participate. The fees established in Section 64860 are based on prior experience with California's certification program, which has been in existence since 1988, and with the initial evaluations of applicants for NELAP accreditation. Many of the program functions are similar, so the prior cost experience of the Department is useful for making cost estimates for the new NELAP accreditation program. In addition, the Department has been collecting workload figures from a group of laboratories that have already applied for the NELAP accreditation program. These have aided in determining the basis

for the new fee schedules established in this regulation. For NELAP accreditation the laboratory must pay a fee once a year, when it applies for re-accreditation, but the site assessment is conducted only every other year after the initial accreditation. There are still costs to the program in these intervening years in which there is no site assessment, because of such things as ongoing consultations, monitoring Proficiency Testing (PT) study results, complaint investigations, accreditation of amendments, and enforcement actions.

The new schedule of fees for NELAP accreditation is similar to the schedule of fees used for the ELAP certified laboratories. It consists of a base or administrative fee and a fee for each field of testing (FoT) or area of analyses. The NELAP base fee is about 3 times that of the ELAP base fee, in order to cover the increased cost to the program of utilizing the more detailed NELAC standards and in interacting with the NELAC organization and other state accrediting authorities.

The NELAP FoT fees are divided into three groups, depending on the complexity of the analytical methods which are contained within that FoT. The more complex FoTs require more scientific skills and expertise to perform the analyses and to document the results. Consequently the more complex FoTs require more assessor time and skills to review and to verify the proper implementation of the methods within the FoTs. There will be a corresponding higher fee for the more complex of FoTs (see attached listing of FoTs and their complexity in Appendix A). As previously noted, the new fees are \$3000 for the base fee and \$750 for the FoTs of low complexity, \$1000 for the FoTs of medium complexity, and \$1800 for the FoTs of high complexity. This fee schedule is based on the information gathered during the NELAP site assessments that the program has already conducted as part of accrediting the first group of laboratories. Another consideration besides the time spent on the part of the assessors is that with the more complex FoTs, the assessors will be a PH Chemist III, an Environmental Specialist III, or a Research Chemist, with a higher salary than the PH Chemist II's who will be conducting the more routine assessments.

As of the middle of December (2000) the program has conducted site assessments on 18 laboratories (4 out of state, 14 within the state: reference Appendix B), which are seeking NELAP accreditation. This group of laboratories is mainly the larger commercial laboratories, with an average of 10 Fields of Testing per laboratory, and the program has sent multiple assessors to each laboratory, as few as two with several smaller laboratories and as many as six to a larger laboratory. The program has had a total of 60 visits by staff members on site assessments and spent about 3480 hours on the assessments (on-site assessments plus the office overhead). Thus each assessor associated with a NELAP assessment is spending over 58 hours per visit. Please refer to Appendix C.

To calculate the cost of these site assessments to the program the audit staff, which consist of Public Health Chemist II's and III's, and Environmental Specialist III's, recorded the number of hours which were spent in pre-assessment and post-assessment activities, as well as the time spent on the on site assessment itself. The hourly rate of pay for these staff members was multiplied by the number of hours sent on the laboratory to determine the assessment cost of the laboratory. This assessment cost has been determined, from the department's experience with the state certification program, to be 45% of the total cost of accrediting a laboratory. This total cost of accreditation is then used to determine the fees charged to the laboratories (see attached breakdown of assessment cost for NELAP laboratories). The costs have ranged from about \$10,000 for a small laboratory with only one medium complexity FoT to over \$50,000 for a large laboratory with 17 FoTs of all complexities. The corresponding fees for these two laboratories are \$4000 for the smaller and \$25,900 for the larger. The total assessment cost has been calculated to a little less than the new NELAP fees for the 18 laboratories which have been assessed. Although fees are collected every year, and laboratory assessments are every other year. During the non-assessment year the program still accrues cost, but not as much as during the site assessment. Therefore over two years the revenues generated from these new fees will be sufficient to cover the cost of accrediting and maintaining the accreditation of a NELAP laboratory.